6. 510(k) Summary as required by 21 CFR 807.92

6.1. Submitter of 510(k)

510(k) owner's name	:	Isodose Control BV
address	:	Maxwellstraat 16 6716 BX Ede The Netherlands
phone	:	+31 318 502950
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name of contactperson	:	Hub van de Bergh
e-mail	:	hvandebergh@isodosecontrol.com
date the summary was prepared	:	April 7, 2009

6.2. Device: Flexiplan

name of the device / trade or proprietary name: **Flexiplan**
common or usual name: Brachytherapy Treatment Planning System
classification name: Remote controlled radionuclide applicator system (per 21 CFR section 892.5700 Product code MUJ)

6.3. Legally Marketed Device(s)

The Flexitron device can be shown to be substantial equivalent to the legally marketed devices cited in the table below.

Device	Manufacturer	510(k) #
Flexiplan	Isodose Control BV	K081112

6.4. Description of the Device

6.4.1. Flexiplan

Flexiplan is a software package which runs on a Windows – based PC and is used by medical professionals to create a radiation therapy plan based on the input entered by the operator.
The isotopes used in the calculations match those which are normally used in High Dose Rate (HDR) and Pulsed Dose Rate (PDR) Remote Afterloaders. The software offers tools to enhance imported images and offers contouring of the planned target volume and organs at risk.
The main use of Flexiplan is to calculate the required dwell times at the pre – determined dwell positions in a uniform way so that the Planning Target Volume (PTV) is treated with the prescribed dose while sparing the Organs At Risk (OAR).
Flexiplan can reconstruct one or more applicators. Based on the contoured target volume and the prescription dose, Flexiplan will calculate the optimal dose distribution for the tumor volume.
Evaluation tools are available to qualify the proposed treatment. The therapy planning is then transferred from Flexiplan to the Afterloader.
The Flexiplan software is intended to be used with the Flexitron Brachytherapy Remote Controlled Afterloading Device.

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The Flexiplan System comprises subjoined listed subsystems:

- Personal Computer
  It executes the Flexiplan software.
- Monitor
  To visualise the treatment planning process.
- Keyboard
  To enter treatment data.
- Mouse
  To select objects on the screen

The PC is used to execute the Flexiplan software and runs under Windows XP Professional or Vista. The hard disk stores patient data and the built in DVD-RW is used for making backup of the Patient Data. The PC can be connected to the hospital network to import Patient Image Data.

6.4.2. Accessory: Frame Grabber

The Frame Grabber allows for direct input of a video signal as available from Ultra Sound Imaging Devices in order to present the image on the screen to visualise the implant.

6.4.3. Accessory: Film Scanner

The Film Scanner allows the user to scan in an X-Ray image to present it on the screen to visualise the implant.

6.4.4. Accessory: Printer

The Printer allows for hard copy of the patients treatment plan and other stored data.

6.4.5. Accessory: Pen Tablet

The Pen Tablet acts as an alternative replacement for the mouse enabling the user to outline more accurately and faster a contour on the monitor.

6.4.6. Accessory: Touch Panel

The Touch Panel acts as an alternative replacement for the mouse enabling the user to outline more accurately and faster a contour on the monitor.

6.5. Intended use of the Device

The Flexiplan is used for the creation of treatment plans for High Dose Rate and Pulsed Dose Rate remote afterloader based brachytherapy. Flexiplan will calculate a proposed treatment course based on imported clinical images and other user entered data. Flexiplan also supports the evaluation of clinical images in calculating the local and global doses.

6.6. Technological characteristics of device compared to the predicate device

The Flexiplan V2.5 Brachytherapy Treatment Planning System has the same technological characteristics as the unmodified device which is cleared onder 510(k) # K081112.

The same as the unmodified device Flexiplan V2.5 is based on a computer system, a monitor for data visualisation, keyboard and mouse for data entry. Optionally a frame grabber may be used with Flexiplan V2.5 for capturing video images.

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6.7. *Substantial Equivalence*

The modified Flexiplan software has the following similarities to the version that previously received 510(k) clearance.

- the same intended use,
- the same operating principle,
- the same technological characteristics.

The differences between Flexiplan V2.5 and its cleared predecessor version do not concern the basic principle of operation nor does it adversely affects the safety or effectiveness of the device.

The conclusion is that Flexiplan V2.5 is, in our opinion, substantially equivalent to the previously cleared unmodified predecessor Flexiplan version.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Mr. Hub van de Bergh
QA & RA Officer
Isodose Control BV
Maxwellstraat 16
Ede, 6716 BX
THE NETHERLANDS

Re: K091145
Trade/Device Name: Flexiplan V2.5
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: MUJ
Dated: April 10, 2009
Received: April 27, 2009

Dear Mr. Hub van de Bergh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

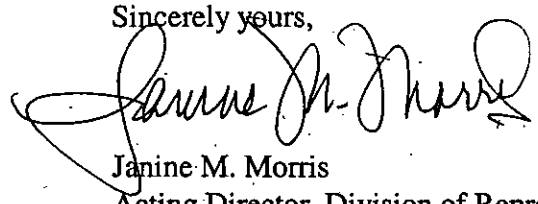
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): pending K091145

Device Name: Flexiplan V2.5

Indications for Use:

Flexiplan is a Brachytherapy Treatment Planning System used by medical professionals. Flexiplan is used for the creation of HDR or PDR treatment plans for remote afterloader based brachytherapy. It especially supports the Flexitron Remote Afterloader from Isodose Control. Flexiplan calculates a proposed treatment course based on imported clinical images and other user entered data. Flexiplan supports the evaluation of clinical images in calculating the local and global dose to organs at risk and target volume.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091145

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